MEDICAID DRUG REBATE DISPUTE RESOLUTION PROGRAM

I. HOW MANUFACTURERS CAN AVOID UNNECESSARY DISPUTES

1) The Manufacturer's Rebate Coordinator Should be Familiar With Various Aspects Of The Company's Product Line

Many disputes arise due to what appears to be excessive units dispensed per prescription of a National Drug Code (NDC) number. Although the units may appear to be inflated, there may be a reasonable explanation or circumstance to justify the "higher than normal" dispensing quantity. These types of disputes might be avoided if the manufacturer's rebate coordinator becomes familiar with several aspects of their company's product line. Key things that the coordinator should know are:

- *Condition/Illness For Which Product Is Indicated*

The product's indication will play an important role in determination of the expected usage of the product. For example, maintenance medications are usually dispensed in larger units per prescription than acute care medications. Additionally, certain diseases, such as AIDS or cancer, may require higher than average dosing or off-label usage of drugs, resulting in a larger number of units per prescription.

- *Correct Product Dosing*

Is the product prescribed twice daily or as needed? By knowing correct dosing, along with the expected duration of therapy, the coordinator can estimate an expected prescription size or typical number of units per prescription. This information may be helpful when trying to identify if an error in pharmacy billings has caused invoiced units to be overstated. As discussed above, certain indications or diseases may require dispensings for more than an average number of units per prescription.

- *Product Formulation*

It is important that the manufacturer's Medicaid drug rebate coordinator know the drug's formulation. Is the product a liquid or a gel capsule? Is the injectable product in solution or a powder-filled vial? The drug's formulation will determine the correct unit of measure for billing and invoicing. Knowledge of the drug's formulation will help the coordinator identify any potential errors in pharmacy billings caused by units billed in the wrong unit of measure.

- *Product Package Size*

The product's packaging size or packaging characteristics may affect the number of units typically dispensed per prescription. For example, a 20 gm tube of cream will have a dispensing quantity typically lower than the 60 gm tube of the same cream. Individual units of a drug packaged together in an unbreakable package may be reported as a kit, rather than as the sum of the individual units. A common error made by pharmacists when billing injectable powder-filled vials is to bill for the capacity of the vial to hold diluent (e.g., 10 ml) rather than to bill "each" for each vial dispensed. A good understanding of the product packaging may help to identify the potential for billing errors to occur.

- *Product Distribution Patterns*

Many manufacturer rebate coordinators review internal product sales reports to determine if a state's reported utilization of a product is consistent with the manufacturer's expected utilization in that state. If a manufacturer chooses to use these reports to make decisions on whether to dispute state utilization information,

the rebate coordinator should be familiar with all of the distribution patterns for their products and determine whether the sales reports are accurately capturing and reporting all state utilization. For example, mail-order pharmacy dispensing, nursing home dispensing, out-of-state wholesalers, group contract purchases, and pharmacies dispensing across state borders are all issues that need to be evaluated in internal reporting.

2) The Manufacturer's Drug Rebate Coordinator Should Ensure That Rebate Information Has Been Accurately Reported to CMS and To Independent Data Sources

There are sometimes instances in which a state may invoice a manufacturer for a product and the manufacturer withholds all or partial payment on the product, not because the manufacturer questions the accuracy of the pharmacy billings, but due to rebate amount per unit issues or product rebate eligibility concerns. By timely reporting to CMS and to independent data sources, manufacturers can help CMS and the states to obtain accurate information so that invoices are correct and so that states do not continue to pay pharmacies for products that are expired or not rebate eligible. Timely and accurate reporting will subsequently preclude related disputes.

Reporting to CMS
Once a manufacturer enters into the drug rebate program, the manufacturer is required to report basic information to CMS. The information provided to CMS is used to develop the Unit Rebate Amounts (URAs) which are sent to states that in turn use the data to prepare rebate invoices. The data reported to CMS from manufacturers must be accurate. Errors in reporting data can lead to errors in the URAs, which can lead to errors in state invoices. As a result, errors in state invoices can lead to unnecessary balances. The following provides the information that the manufacturer is required to report to CMS and the time line for reporting.

WITHIN 30 DAYS OF ENTERING INTO THE MEDICAID DRUG REBATE PROGRAM

- *Baseline Data*

Baseline data is required for ALL drug products that have an NDC. Baseline data provides a "profile" of each product. Baseline data forms the basis for CMS' data system, which is called the Medicaid Drug Rebate (MDR) System. Baseline data provides the information about a manufacturer's product that is needed in order to determine how a rebate should be calculated. Baseline data fields may be found in the Operational Training Guide, Section F.

WITHIN 30 DAYS AFTER THE END OF EACH CALENDAR QUARTER

- *Best Price (BP) and Average Manufacturers Price (AMP)*

Manufacturers are required to submit BP and AMP information to CMS within 30 days of the end of each quarter. There is a distinct difference between the calculations of BP and AMP. The following guidelines should be used in conjunction with official CMS instruction to determine the BP and AMP:

- Best Price (BP) **-** BP is the **LOWEST PRICE AT** WHICH A PRODUCT IS SOLD regardless of the package size. The BP IS NOT a weighted average (see AMP). ALL package sizes of a product must contain the same BP. BP is submitted for all drugs categorized as "S" (Single-Source) and "I" (Innovator) drugs, but **NOT** for "N" (Non-Innovator Multiple-Source) drugs.

- Average Manufacturers Price (AMP) - AMP is a per unit, per product code (NDC#3) **WEIGHTED AVERAGE** based on sales. If a drug is distributed in multiple package sizes, there will be one "weighted" AMP for the product, which will be the same for all package sizes. ALL package sizes of the same product code must have the same AMP. AMP is required for EACH NDC.

Manufacturers should take measures to verify that this information is reported on time and in accordance with established CMS formats. Because CMS actually calculates the URA on each NDC from the submitted BP and AMP data from the manufacturer, rounding differences may sometimes occur between CMS' calculation and the manufacturer's calculation.

- *Drug- Category*

For purposes of the Drug Rebate Program, the Drug Category designates whether a drug is classified as a Single-Source (S), Innovator (I), or Non-Innovator Multiple-Source (N) drug. The Drug Category is one of the "Baseline" data fields. The drug category will determine the rebate percentage. Generally speaking, the S & I drugs are brand name drugs and the N drugs are generic drugs.

- *Date Product Entered Market*

The product market date, for purposes of Medicaid drug rebates, is defined as the date the product entered the market and was offered for sale. If marketed prior to 10-01-90, the date entered market would be the first day of the first month that the drug was mareketed for the entire month; othewise, it will be the actual date the product was marketed.
The rebate coordinator should be familiar with the market date for the manufacturer's product because it will affect the URA CMS calculates and sends to the states.

- *Correct Listing Of Unit Types/Units Per Package Size (UPPS)*

Manufacturers should review information from CMS, the Operational Training Guide, as well as other data sources such as the Red Book and First Data Bank, to ensure that UNIT TYPES and UPPS are listed correctly with all of these sources. Unit types and UPPS must be developed together. A unit type MUST BE designated as the SMALLEST identifiable amount for which a product can be sold. There are seven specific unit type values and "EA" (each) for some products (e.g., tablet or capsule for solid dosage forms, milliliter for liquid forms, and grams for ointments). ALL PRICING IS **BASED ON THE UNIT TYPE**. If a unit type is "ML," then pricing reflects one ML for the product.

The value for the UPPS will vary depending on whether the product package can be broken and dispensed in smaller amounts. For example, if a product with a unit type of "CAP" (capsule) comes in a bottle with 100 capsules and can be dispensed in the amount of 10, 20, 30, etc., capsules, then the UPPS is "1." However, when a product **MUST BE** dispensed as it is packaged (cannot be broken into smaller units), the UPPS will be the actual size of the package. For example, a 12-pack of suppositories (which is the standard dosage for some products) must be dispensed as a 12-pack, then the UPPS is "12".

- *Follow Up To Ensure Corrections/Edits Are Made*

The use of outdated or otherwise incorrect pricing information by CMS when calculating rebate information will lead to incorrect calculations by states, and therefore create unnecessary balances. In order to avoid this, once a manufacturer is notified by CMS that its pricing data failed to pass edits, the manufacturer should

promptly contact CMS to resubmit correct data. The manufacturer should also inform any independent data sources, such as First Data Bank and the Red Book, of any changes, as these independent data sources also serve as information resources for states and pharmacy providers.

CMS processes the quarterly pricing data and sends edit reports to manufacturers. Edit reports are sent to the manufacturer when data submitted to CMS falls into an "alert" message or data is "rejected." Quarterly pricing data can be "rejected" for a number of reasons including:

- AMP/BP is not numeric
- AMP/BP is missing
- There is no Baseline record on CMS' MDR for the NDC

There are also several reasons the edit report will contain an "alert" message.

- BP is greater than the AMP
- DESI indicator change attempted

The manufacturer should make every effort to correct information on the edit reports and return the updated data to CMS before the MDR system is shutdown for rebate calculations (about 45 days after the end of the quarter). See Section G of the Operational Training Guide.

- *Termination Date/Expired Drugs*

The rebate coordinator should be aware of which drugs in the company's product line are no longer manufactured. There are a number of reasons a drug may no longer be manufactured, including: the drug being pulled from the shelf for health or safety reasons; the drug being replaced by an improved version; or the drug being discontinued due to low sales. In any case, the Termination Date must be reported to CMS. If the drug is pulled from the shelf for health or safety reasons, the Termination Date is the date removed from sale. However, if the drug is terminated for other reasons, the Termination Date is the shelf-life expiration date of the last batch sold.

Manufacturers are required to report pricing information for terminated or expired drugs for FOUR QUARTERS beyond the termination date. Manufacturers must pay rebates for discontinued products that still have effective shelf lives.

- *Selling of Product to Another Manufacturer (NDC)*

The manufacturer whose 5-digit labeler code (first five digits of the NDC numbre) appears on the product sold is responsible for paying rebates on that product. If the original manufacturer of the product sells the product to another manufacturer**/repackager/relabeler** and the original manufacturer's labeler code still appears on the product, the original manufacturer should forward rebate information to the new owner or make whatever arrangements necessary to assure that rebate payments are made timely. Since the original manufacturer is responsible for rebates on that product, the original manufacturer should verify that the new owner has properly paid the rebates due.

- *Changes in Manufacturer Contacts*

In addition to pricing data, manufacturers should notify CMS as soon as possible when a change occurs with respect to the contact person(s) and their correct address and information. This will avoid any potentially lost invoices due to states receiving and utilizing incorrect and/or outdated contact information from CMS. Updates on

manufacturer's contacts help assure that states send invoices to the appropriate person and assist in promoting better communication. Changes should be reported to CMS on form CMS-367a, found on page M4/5 of the Operational Training Guide, and faxed to (410) 786-0390.

- *Reporting Penalties and Suspension/Termination*

The manufacturer needs to be aware of the penalties involved in failing to report information to CMS and in reporting false information to CMS. The National Rebate Agreement and statute provides that a manufacturer may be assessed a civil monetary penalty of $10,000 for each day that the manufacturer fails to report AMP and BP or the list of covered outpatient drugs to CMS. In addition, a manufacturer that knowingly provides false information may be assessed a civil monetary penalty of $100,000. The same civil monetary penalty of $100,000 may be assessed if a manufacturer refuses to respond to a request for pricing information from CMS or provides false information. Additionally, CMS may pursue suspension or termination actions for good cause reasons.

Reporting to Independent Data Sources

Manufacturers are not required to report data to independent data sources. However, many state Medicaid programs and pharmacy providers utilize drug data from independent data sources such as MediSpan, First Data Bank, and Redbook. For this reason, manufacturers should provide basic product information for all NDCs (e.g., product description, product indication, AWP, unit type, package size, etc.) to independent data sources. In addition, manufacturers should provide updates on pricing information for all NDCs. The manufacturer should make sure that the unit type and UPPS provided to independent data sources is accurate. For example, if a manufacturer uses 30 ML rather than 28.7 ML = 1 oz. for a tube of ointment, the manufacturer should report this information to the independent data sources. If unit type and UPPS information is inaccurate, then the state invoice may be inaccurate, thus leading to a dispute.

3) The Manufacturer's Rebate Coordinator Should Have An Understanding Of State Reimbursement Processes

State Medicaid programs have some discretion in establishing reimbursement policies for services covered by the Medicaid Program including drugs. These reimbursement policies usually involve payment to pharmacies for drug cost based on a percentage of AWP. There are many variations of reimbursement, including direct pricing, estimated acquisition cost (EAC), State maximum allowable cost (MAC), Federal upper limit (FUL), usual and customary, etc. The manufacturer's rebate coordinator should be aware of the various reimbursement processes for the states. The coordinator should also be aware that many pharmacies may be able to purchase drugs at prices far below AWP by taking advantage of discounts for volume purchasing, early payment of invoices, etc. Some state may provide this information on their web page.

- *Medicaid Rate vs. Usual and Customary*

A number of Medicaid Programs have established definitions of usual and customary as a way to define pricing for drugs paid for by the Medicaid program. In general,

states establish "usual and customary" definitions to assure the Program is charged the lowest price for drugs. Usual and customary pricing usually reflects the pharmacy's everyday price charged for a drug product. This price may be lower than the Medicaid program's allowed amount if the pharmacy sells the product as "loss leader," for example, or if the pharmacy competitively prices the product.

- *Most Favored Nation Policies*

Some states invoke "most favored nation" status in order to receive the lowest prices from pharmacies that those pharmacies charge other payers. "Most Favored Nation" policies help ensure the lowest price for a drug product by providers is billed to the Medicaid Program. The state Medicaid program will often refuse to reimburse at the rate being offered by the Medicaid program if a lower price is being charged to other entities (e.g., HMOs, PCS, MediMet, etc.).

- *Federal Upper Limits*

In 1987, regulations limited the amount that Medicaid could reimburse for drugs with available generic drugs under the Federal Upper Limit (FUL) Program. These limits are intended to assure that the Federal government acts as a prudent buyer of drugs. The concept of the FUL program is to achieve savings by taking advantage of the current market prices.

Until the passage of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90), the FUL could be established only if all versions of a drug product had been classified as therapeutically equivalent (A-rate) by the FDA in its publication "Approved Drug Products with Therapeutic Equivalence Evaluations" and at least three suppliers were listed in the current editions of published national compendia. OBRA '90 expanded that criteria and permitted the establishment of a FUL for a drug product if there are three (or more) versions of the product rated therapeutically equivalent (A-rated) regardless of the ratings of other versions (B-rated). and at least three suppliers are listed in the current editions of published national compendia.

The states inform their pharmacies of the FUL reimbursement limits as the maximum cost for which the pharmacists can be reimbursed for these products.
Note: At the current time, CMS publishes the FUL list on their web page.
http://www.cms.hhs.gov/medicaid/drugs/drug10.asp

- *State MAC Pricing*

Some states have implemented a State Maximum Allowable Cost (MAC) program in addition to the Federal Upper Limit (FUL) program. The prices that states set for drugs in a State MAC program represents the maxium cost which the pharmacists can be reimbursed for those selected drugs. The criteria for setting the State MAC prices vary from state to state. Some states provides information on their MAC programs on their web page.

- *Dispensing fees*

Pharmacies participating in the Medicaid program are allowed to charge Medicaid a "reasonable" dispensing fee per prescription dispensed. Each state Medicaid program has the discretion, with CMS approval, to determine what "reasonable" means for their individual programs. Thus, the dispensing fee allowed by state Medicaid programs will vary from state to state. The rebate coordinator should be aware that states usually pays pharmacies a dispensing fee per prescription filled, and should be familiar with each state's dispensing fee. This will assist the rebate coordinator in evaluating the state's reimbursement on a drug. Again, each state may vary with

regard to payment of dispensing fees, including dispensing fees on refill prescriptions, third-party prescriptions, or drugs priced at usual and customary rates.

- *Recipient Copayment/Deductible*

Some states may require Medicaid recipients to make a copayment or to meet a deductible in order to receive drugs through the program. Recipient copayments will reduce the reimbursed amount for drugs and should be considered when analyzing the invoice for dispute. The copayment or deductible required may vary from state to state.

- *State Prescription Limits/Regulations For Products*

Some drugs or drug categories are often regulated by state Medicaid program policy concerning the number of units that can be dispensed per month or per prescription. Some states establish prescription limits per month (e.g., 3 per month). Monthly prescription limits may increase the number of days' supply per prescription and can result in large quantities dispensed per prescription. For example, some states regulate the duration of acute care dosing of Histamine H_2 Antagonists. Other states may require that birth control pills be dispensed in a three-month supply per dispensing. The manufacturer's rebate coordinator should try to become aware of state policies on prescription limits that may explain why dispensing averages may appear different from other state averages.

- *Excluded Drug Categories*

Certain drug categories may be excluded from the Medicaid drug rebate program, and are therefore considered "non-rebatable." Such products include vaccines, products for weight control, hair growth, products for smoking cessation, fertility treatments, syringes, etc. In addition, potentially excluded are products that require monitoring services to be purchased exclusively from the manufacturer or designee. Permissible restrictions or exclusions are at the discretion of each state. This provision may be found in Section 1927 of the Social Security Act.

- *Third-Party Liability (TPL)*

In some cases, Medicaid recipients may have other insurance coverage in addition to Medicaid. In these instances, Medicaid is considered to be the payer of last resort. TPL will reduce the reimbursed amount and should be considered when analyzing the state reimbursement amount. As a reminder, if a state Medicaid agency paid **any** portion of a drug claim to the provider, for purposes of the drug rebate agreement, the manufacturer is liable for the payment of rebates for those units of the drug.

- *State Generic Substitution Laws*

Many state Medicaid programs have laws governing generic substitution. The manufacturer's rebate coordinator should also be knowledgeable of state generic substitution laws.

4) The Manufacturer's Rebate Coordinator Should Become Familiar With Heavily Discounted Prices

Sometimes, manufacturers will enter into individual agreements with different pharmacy providers whereby the dispensing pharmacy will receive a purchasing discount(s) from the manufacturer. These discounts may explain how pharmacies can use branded products and accept a reimbursement lower than typical for the branded product. The rebate coordinator should be aware of which pharmacies have entered into such agreements by verifying internal discounts or contracts with pharmacies prior to disputing based on an analysis of the state's reimbursement.

5) The Manufacturer's Rebate Coordinator Should Reconcile Detailed State Utilization Data (Sud) From External Data Sources With The State Invoice To Make Sure They Correspond with Each Other

Manufacturers should compare detailed SUD, especially data obtained from external data sources, with the invoice information submitted by the state to ensure that they correspond. There are many reasons why detailed SUD, whether obtained from the state or from external data sources, may vary from the submitted invoice. One common reason that variances occur is that some prescriptions may not have been captured when generating the data or may have been erroneously included. For example, Public Health Service (PHS) billings excluded from invoices may not have been extracted when generating utilization data for a manufacturer or for external data sources. The manufacturer's rebate coordinator should have an understanding of why variances occur in order to avoid disputing units that were never invoiced. Examples of how variances may occur include:

- prescriptions not captured by third-party data, such as physician dispensings/prescriptions;
- units from compounded prescriptions originally billed under a "dummy" NDC;
- units from PHS prescriptions (in/out of data); and
- nursing home prescriptions (sometimes pulled from a different file).

6) Learn From Previous Resolutions

Manufacturers can proactively avoid disputes by identifying recurring disputes. The manufacturer should call the state and identify the recurring problem. The state can then work with providers to correct billing for the NDC and possibly perform upfront edits to resolve the problem before the invoice is sent to the manufacturer. For example, some states have point-of-sale (POS) systems that round units which may result in disputes. The manufacturer's rebate coordinator should be aware of which states have POS systems which may result in discrepancies in units reported due to rounding. The manufacturer should contact the state to try to rectify the problem instead of disputing the state invoices every quarter.

7) Work With States To Resolve Discrepancies Before They Become Disputes

States should submit invoices to manufacturers within **15 days** after receiving Unit Rebate Amount (URA) data on the quarterly tape from CMS. Upon receipt of the state invoice, the manufacturer should review the invoice for any discrepancies. Manufacturers are required to pay rebates to states for all rebate eligible NDCs invoiced, except those which are disputed. A manufacturer may also pay the full rebate amount invoiced and still dispute the amount they feel is incorrrect, indicating such on the Reconciliation of State Invoice (ROSI). Note: disputes can only be based on the number of units invoiced per NDC.

Manufacturers are required to respond to a state invoice, either by paying the invoice or withholding payment on units submitted by the state which the manufacturer feels are questionable. The undisputed amount of the rebate must be paid within 38 calendar days from the date the state utilization data was postmarked. Failure to pay for all invoiced units in the required time frame will result in the beginning of the dispute resolution process, and the potential accrual of interest liability.

Manufacturers are encouraged to attempt to reconcile issues with SUD within the 38 calendar day time period. The manufacturer may request claims detail information from the state in order to verify billing information or may request that the state research the NDC and issue a response to questions the manufacturer might have. This quick approach to resolving questions regarding state invoices may prevent the need for a dispute. Timely research will also make it easier for pharmacy providers to locate records to verify billing information.

8) Educate New Staff

It is essential that manufacturers make arrangements for the education of new staff to ensure a smooth transition when replacing its rebate coordinator. New staff should be familiar with the Medicaid program and drug rebate legislation. In addition, new staff should become familiar with the information provided on our web page, the *Medicaid Drug Rebate Program Operational Training Guide,* and the numerous Drug Manufacturer Releases from CMS. This also includes ensuring that new staff is familiar with internal company policies, such as supplemental rebates, contracting language, etc.

9) Maintain Documentation

Complete and accurate records of all invoices paid, contacts with states, etc., should be maintained. The lack of adequate and accurate documentation prolongs the process of rebate payment, as well as the dispute resolution process. The maintenance of complete files will also help prevent problems due to manufacturer staff turnover from affecting the timely payment of disputes or resolution of outstanding disputes.

THE PROCESS OF MEDICAID DRUG REBATE DISPUTE RESOLUTION:
TOP TEN STEPS FOR MANUFACTURERS

1. SCHEDULE/PRIORITIZE/UNDERSTAND RESOURCES

2. EXAMINE INTERNAL RECORDS TO DETERMINE UNPAID REBATE OR DISPUTE BALANCES. SIMULTANEOUSLY REQUEST AND LOOK AT STATE RECORDS TO COMPARE STATE'S RECORDS OF PAYMENT, RECEIPTS, INVOICED AMOUNTS, ETC.

3. AGREE ON A PROCESS THAT LEADS TO RESOLUTION

4. RECONCILE DIFFERENCES DUE TO ACCOUNTING BOOKKEEPING ERRORS

5. RECONCILE UTILIZATION DATA DISPUTES

6. AGREE TO NECESSARY UNIT ADJUSTMENTS FROM UTILIZATION DISPUTE DISCUSSION AND DOCUMENT APPROPRIATELY

7. COMPARE "CORRECTED" UNITS AND RATES TO RECORDS AGAIN TO DETERMINE FINAL DOLLAR BALANCES DUE FOR RESOLUTION

8. COMPLETE RESOLUTION ACKNOWLEDGMENT (RESOLUTION LETTER)

9. ISSUE RESOLUTION PAYMENTS AND INTEREST WITHIN A REASONABLE TIME PERIOD

10. POST RESOLUTION PAYMENTS AND DOCUMENT RESOLUTION CLOSURE

II. BEST PRACTICES IN MEDICAID DRUG REBATE DISPUTE RESOLUTION FOR MANUFACTURERS

The following discusses the Best Practices for Manufacturers in the Medicaid Dispute Resolution process. The Dispute Resolution process begins when the manufacturer notifies the state of a unit dispute. The dispute ends when the manufacturer and state reach resolution on all disputed units.

Each dispute may be unique, however, the process of Dispute Resolution should adhere to the following guidelines.

1) Schedule/Prioritiz/Understand Resources Available

Manufacturers should work with states to identify common priorities in order to resolve disputes. Aged disputes and those involving large dollar amounts should receive priority when both parties are attempting to decide when to begin working on resolving their disputes. In addition, as manufacturers attempt to get all balances to zero, they should target those states who are most capable and willing to participate first, as those disputes may be easily resolved.

Both parties must understand the resource capabilities of each side and understand the limitations. The manufacturer needs to consider its own staffing resources, as well as the staffing resources of the state. This directly ties into scheduling, because most scheduling occurs with the understanding of each party's capabilities. For example, a state may be working on end of fiscal year requirements and may therefore not have the resources to devote to resolving disputes with a particular manufacturer at that time. In instances where resources, especially staff and time, are an issue, both parties can reach an agreement to begin resolving their disputes at a later time. That time should be specified, however, as the goal should be to resolve disputes as soon as possible.

Another important resource issue for manufacturers to keep in mind is the technological capabilities of the states with whom they are attempting to resolve disputes. States with automated systems may have the capability to generate the information necessary to resolve disputes more quickly than a state with a manual system for information retrieval. In these instances, manufacturers may wish to consider attempting to work with those states who have more electronic capabilities first, allotting more time for those states whose systems' capabilities may not be as advanced.

Manufacturers should seek CMS Regional Office DRP Coordinator assistance with states that remain uncooperative after attempts have been made to initiate the dispute resolution process.
Note: The names of CMS DRP RO Coordinators may be found on the DRP web page.
http://www.cms.hhs.gov/medicaid/drugs/drp/drpcoor.pdf

2) Examine Internal Records To Determine Unpaid Rebate Or Dispute Balances. Simultaneously Request And Examine State Records To Compare Data

In order to begin dispute resolution efforts, the manufacturer should examine internal records to determine, by NDC, the number of any unpaid units and unpaid dollar amounts owed to the state. At the same time, the manufacturer should request a copy of state records to compare the manufacturer's accounting of balances outstanding with the state's assessment of amounts due. This comparison may assist in prioritizing and scheduling work efforts and exchange of information during the dispute process.

3) Agree On A Process That Leads To Resolution

Communication between the state and the manufacturer is a key element in the successful resolution of disputes. The initial phase of dispute resolution involves the exchange of information between the state and the manufacturer and informal negotiations and an assignment of duties between both parties. The manufacturer and state should agree on an approach that would best produce a resolution to the dispute.

4) Reconcile Differences Due To Bookkeeping/Accounting Errors

Due to the tremendous volume of financial postings involved with invoicing and the recording of manufacturer payments, both states and manufacturers may show outstanding rebate balances because of bookkeeping and accounting errors, rather than actual disputed issues. These balances are usually a result of discrepancies in the posting of rebate payments or a result of discrepancies in unit rebate amount.

Account Related Differences Due to Payment Receipt and Posting Discrepancies

Manufacturers should strive to compare state and manufacturer records to ascertain that payments and invoice details are identically recorded. Discrepancies should be jointly researched and resolved with state assistance. Manufacturers should be willing to assist states with proper allocation of payments, especially for payments made prior to the use of Reconciliation of State Invoice (ROSI) vouchers when payments may not have been clearly documented.

Manufacturers should verify that manufacturer-calculated rates match rates calculated and reported by CMS. Likewise, state reported rates should match those reported by both manufacturers and CMS. Control procedures should, at a minimum, include six-digit comparisons with CMS quarterly reports and with state's quarterly invoices. Discrepancies should be promptly researched and resubmitted to CMS, through prior period adjustment (PPA) reporting procedures (using the Prior Quarter Adjustment Statement (PQAS)), when appropriate.

Differences reported on state invoices should be pursued with the states. The resolution process should not be delayed while rate discrepancies are being researched. Parties are encouraged to expedite dispute resolution using manufacturer rates.

Some of the most common examples are:

Error. Misapplied payments
Solution: Supply payment voucher detailing application

Error. Duplicate payments

Solution: Supply check copies

Error. Missing rate adjustment
Solution: Supply rate information

Error. Rounding differences (state calculated vs. manufacturer calculated rebate amounts due)
Solution: Agree to resolve rounding differences
Error. Products sold to other manufacturers, but invoiced under original owner's labeler code
Solution: Invoiced manufacturer provides invoice information to new product owner for payment of rebates. Assure that new owner clearly indicates on payment voucher the invoiced NDC being rebated.
NOTE: The manufacturer whose labeler code appears on the product sold is responsible for paying rebates on that product.

Error. Miskeying of invoice information by manufacturer
Solution: Correct any miskeying errors

Error. Invoices not received by manufacturer
Solution: Obtain and pay missing invoices (including interest, if applicable)

5) Reconcile Unit Disputes

Disputes occur when a manufacturer questions the correctness of invoiced units. Such disputes can include units for which payment is withheld at the time the original invoice is paid, and units originally paid but later (retrospectively) questioned based on new information (e.g., detailed data, etc.). A manufacturer can only withhold payment for disputed units and must pay rebates (plus any applicable interest) for all undisputed units.

There are many reasons why manufacturers might question utilization information reported on state invoices. Some of the most common reasons for utilization disputes are listed below.

Problem: Unit Types (must be the smallest identifiable amount). Unit type reported in invoiced units does not match unit type of rebate amount per unit.

Problem. Units dispensed do not correlate with the Medicaid reimbursed amount.

Problem. Keying errors

Problem. Processing problems (Field justification problems, inappropriate conversions, etc.)

Problem. Rounding problems/incorrect decimal position

Problem. PHS billings

Problem. Terminated/expired drugs

Problem. Units billed under wrong NDC

Problem. Products sold to other manufacturers

Problem. Non-covered drugs/devices/services

BEST PRACTICES IN MEDICAID DRUG REBATE DISPUTE RESOLUTION FOR MANUFACTURERS

Before initiating a dispute, a manufacturer should consider the cost effectiveness of the dispute. The manufacturer may decide to pay the disputed invoice if it is not deemed cost-effective to pursue dispute resolution efforts. If not, the dispute resolution process continues.

Once the manufacturer decides to pursue a disputed issue, the manufacturer must provide the state with a detailed reason for the dispute so that the state can research the issue appropriately. (The Reconciliation of State Invoice (ROSI) is mandated for use by manufacturers to uniformly explain the adjusted rebate payments to state and allows for choosing codes to explain for adjustments and disputes per NDC.) If the manufacturer has claim detail utilization data available, the manufacturer should provide the state with a list of claims/providers in question for each disputed NDC in order to expedite research efforts for the state. Manufacturers should take time to validate claim detail information they have available to make sure that the number of claims and number of units in the detail data match invoice totals. Oftentimes, claim details obtained from the state or from third-party vendors contain claims, such as PHS billings, which were extracted during invoice generation and thus were not included in invoice totals. In other cases, claims invoiced may not be included in data obtained by third-party vendors. This is often the case with adjusted claims, physician dispensings, compounded prescriptions, and, on occasion, nursing home claims. Manufacturers need to know the validity of claim detail information as it relates to invoice information before using the data to analyze dispute issues. Manufacturers should provide last lot expiration dates to the states for all NDCs invoiced which are no longer rebate eligible.

After the state receives the ROSI and/or the PQAS, the state and manufacturer should discuss, by NDC number, the items disputed and the reason for dispute. The state should contact the manufacturer in writing or by telephone to discuss, by NDC number, the dispute, the reason for dispute and should present a report to the manufacturer of preliminary response to the dispute resolution. If the dispute is resolved, the manufacturer and state must both maintain supporting documentation of the resolution.

If the dispute is not resolved, the manufacturer should reach an agreement with the state as to a reasonable timeframe for the state to conduct the research necessary to provide requested information to the manufacturer. If the state makes a request for further information from the manufacturer, the manufacturer should honor that request as soon as possible so that the process will not be hampered.

The manufacturer may request additional documentation from the state to support invoiced utilization data. Additional documentation may include:

- Drug utilization data
- Zip-code level utilization data
- Pharmacy level utilization data
- Sampling of pharmacy claims

- Historical claims data

The state should attempt to resolve questions concerning data by reporting the findings of state research or by providing the documentation requested by the manufacturer. The type of data provided by the state must match the type of data requested by the manufacturer. Once the manufacturer has received the requested research from the state, the manufacturer should evaluate the information and determine if the dispute can be resolved.

If a manufacturer's concern involves a large number of claims for a given NDC, the state may perform a random sample of pharmacies to expedite time and research efforts. The sample size needs to be mutually agreeable to both the state and manufacturer.

Once the manufacturer is satisfied with the state's response to disputed issues, the resolution, in terms of corrected units, should be documented and made part of the drug rebate file.

6) Agree To Necessary Unit Adjustments From Utilization Dispute Discussion and Document Appropritely

Manufacturers and states should come to an agreement that is mutually acceptable to both parties based on data acceptable by both parties. A resolution can be made when state utilization data are corrected, when there is agreement that invoiced units are correct, OR both parties agree to a resolution based on mutually acceptable data that is more representative of actual Medicaid utilizaton. Any resolution reached should be appropriately documented, listing action steps taken by each party, results of all research conducted, unit changes made, and any follow up which is anticipated. A copy of resolution documentation should be kept in the manufacturer's files, as well as the state's files.

7) Compare "Corrected" Units and Rates to Records Again To Determine Final Dollar Blanaces Due For Resolution

Once the manufacturer and the state have reached an agreement regarding units and rates, and made any mutually agreed upon changes to their respective records, both parties should compare records once again to make sure that they agree as to the final dollar amounts required to bring balances to zero. Interest payments, if applicable, should be discussed and ageed upon.

8) Obtain Reconciliation Statement From State

Once the manufacturer and state have reached a point where their records correspond with the corrections that were mutually agreed to, the manufacturer should obtain a reconciliation statement/letter from the state. The statement/letter should reiterate the state's agreement that the balances specified in the statement accurately reflect the amounts needed to satisfy all unit issues. The statement should also specify the expectation of interest payment on balances due the state, if applicable. The appropriate state representative should sign the letter and a copy should be placed in the manufacturer's files.

9) Issue Resolution Payments And Interest Within A Reasonable Time Period

Upon receipt of the reconciliation statement/letter from the state, the manufacturer should issue a resolution payment, including any applicable interest, promptly within a reasonable time period. If the manufacturer is not able to include interest in the payment sent to the state, it should include a letter with the payment stating that the accumulated interest will be calculated and paid upon receipt of the state's signed agreement to the resolution. The manufacturer is responsible for calculating interest due to states on unpaid or late rebate payments. Payment of interest is not optional.

It is important to remember that a resolution may not only result in a manufacturer payment to the state, but may also result in a credit or reimbursement payment from the state, including any applicable interest. A credit due to a manufacturer as a result of dispute resolution findings may be taken against payment of a future invoice. Proper documentation of this application should be provided to the state for accurate posting.

10) Post Resolution Payments and Document Closure

Once the manufacturer has issued a resolution payment, including interest, to the state, or received a credit from the state, both parties should continue to work to post balances to zero. This may include ongoing discussions and the sharing of supporting documentation to ensure that both parties have all necessary information to post a zero balance. Once both parties have reached agreement and are able to post a zero balance, that agreement should be documented and maintained in both entities' files.

III. WHAT SHOULD MANUFACTURERS DO IF THE PROCESS FAILS?

1) Attempt To Go Through The Dispute Resolution Process/Encourage Other Party To Attend DRP Meeting

If repeated attempts to work with a state to resolve disputes remain unsuccessful, the manufacturer may want to consider encouraging the state to attend one of the DRP meetings. These meetings provide a setting in which states and manufacturers can often meet with several other parties during the course of the week, thereby providing a venue for resolving multiple disputes in a short period of time. In addition, CMS staff is present at the meetings and can serve as facilitators in the event that some difficult or seemingly unresolvable issues arise.
Our web page provides information and schedule for the National DRP Meetings:
http://www.cms.hhs.gov/medicaid/drugs/drp/default.asp

In addition, if the Drug Rebate Dispute Resolution Process for manufacturers fail, the manufacturer may require a state to schedule a hearing at any stage of the process if the state does not take the required actions of the dispute resolution process. Options other than a state hearing include:

- Mediation Review
- Non-Binding Arbitration
- Binding Arbitration
- Administrative Hearing

2) Contact CMS Regional Office To Try To Get The Other Party Engaged And To Encourage Them To Attend A DRP Meeting

If a manufacturer finds that after repeated attempts to resolve a dispute with a state remain unsuccessful, it may be necessary for the manufacturer to contact the appropriate CMS RO DRP Coordinators and request their intervention. The CMS RO can assist a manufacturer in persuading a state to begin the resolution process with the manufactureror.
The RO DRP Coordinator will keep Central Office (CO) informed of dispute issues.

Prior to contacting the RO, the manufacturer should make sure to differentiate between states that are unable to participate and those that are simply unwilling to do so. The manufacturer may want to consider arranging with a state that is unable to participate at that time (due to, for example, staffing or resource issues) to work on resolving their dispute at a later date. The state may simply be attempting to resolve aged or large dollar disputes with other manufacturers and may not currently have the resources to address the manufacturer's dispute at that time.

For states that are simply unwilling to enter into dispute resolution discussions, the intervention of the CMS RO DRP Coordinator may provide some assistance in getting that state to the discussion table.
Note: The names of CMS DRP RO Coordinators may be found on the DRP web page.
http://www.cms.hhs.gov/medicaid/drugs/drp/drpcoor.pdf

3) If Necessary, Contact CMS

If a manufacturer has exhausted all other options, including trying to reach an agreementwith a state to begin resolving the dispute at a later date and involving the CMS RO representative, and has not yet been able to engage the state in dispute resolution discussions, it may be necessary to seek the intervention of the CMS CO DRP Team. They will work closely with the DRP RO Coordinators in an effort to assist.